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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/258,947	03/01/1999	JONATHAN L. MILLER	011.00117	4588

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/29/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/258,947

Applicant(s)

Miller et al.

Examiner

G.R. Ewoldt

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/22/02 and 5/21/02.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 11 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/22/02 has been entered.

2. Claims 9 and 11 are pending and being acted upon.

3. Applicant is advised that the invention under examination in an RCE will consist only of the invention previously under examination at the time of final rejection. The invention under examination at the time of the previous final rejection (excluding the antibody of canceled Claim 7) consisted of a peptide that bound to a second peptide, said second peptide consisting of SEQ ID NO:174. As such, Applicant's new recitation of a peptide that binds second peptides having amino acid sequences of SEQ ID NOS:1-21, 23-75, or 77-81 comprises an improper attempt to place additional inventions under examination. Of the aforementioned sequences, only SEQ ID NOS:1, 3-6, and 8 consist of species of degenerate SEQ ID NO:174. As such, the invention under examination will consist of a peptide that binds a second peptide having the amino acid sequence as shown in SEQ ID NOS:1, 3-6, and 8 only.

4. In view of Applicant's amendment canceling Claim 7, filed 2/22/02, the rejection of Claim 7 under the first paragraph of 35 U.S.C. 112 has been withdrawn.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 9 and 11 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention,

for the reasons of record as set forth in Paper Nos. 12 and 16, mailed 11/20/00 and 88/10/01, respectively.

Applicant arguments, filed 2/22/02, have been fully considered but are not found persuasive. Applicant argues that, "In regard to claims 9 and 11, the identification of peptides that bind to these particular mimotopes is routine in the art, and the methodology is disclosed in the specification," and "Furthermore, numerous references which disclose methodology for identifying anti-mimotope peptides that bind to particular mimotope peptides are cited in the specification." Applicant is advised that the ability to identify, or enabling methodology, are not standards by which the written description requirement is met. The specification discloses just four closely related peptides (SEQ ID NOS:94, 104, 105, and 107), all of which bind the same single second peptide (SEQ ID NO:1), that *might* comprise the claimed invention. Note that none of the four peptides have been shown to comprise the recited three dimensional structural limitation of Claim 9. All four of these peptides are 10mers, therefore no peptides (other than 10mers) of "3 to about 100 amino acid residues in length," comprising any of the functional limitations of the claims have been described. Note also that the claims recite the claimed peptides by functional characteristics alone. Applicant admits that "The issue for the subject application stems from the fact that all of the anti-mimotopes do not have a common structural feature in the sense of a common or consensus amino acid sequence." Thus, none of the peptides of the instant disclosure have been described by structure and function, therefore, it remains the Examiner's position that the specification discloses an insufficient number of species to describe the claimed genus.

7. Claims 9 and 11 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most nearly connected to make and/or use the invention, for the reasons of record as set forth in Paper Nos. 12 and 16, mailed 11/20/00 and 88/10/01, respectively.

Applicant arguments, filed 2/22/02, have been fully considered but are not found persuasive. Applicant argues that "the claims, in addition to being limited in regard to the particular mimotope sequences, are also limited to those peptides that inhibit ristocetin induced aggregation of platelets. The identification of such peptides which have this desired functional property can be routinely done using, for example, the methodology disclosed in the specification at page 38, line 13 through page 40, line 20, "Aggregation Studies" and "Synthesized Peptide". Identifiable functional limitation is combined with the structural description in relation to SEQ ID NOS: 1-21, 23-75 or 77-81, applicants contend that an enabling and adequate written description is provided for the invention as now claimed." It is the Examiner's position that the claimed peptides are defined exclusively by functional characteristics and not by any structural characteristics (see previous paragraph). Applicant points to the "structural limitations of SEQ ID NOS: 1-21, 23-75 or 77-81, however, said SEQ ID NOS: comprise peptides to which the claimed peptides bind and not the claimed peptides themselves. Thus, the structural characteristics of SEQ ID NOS: 1-21, 23-75 or 77-81 comprise only functional characteristic of the claimed peptides. Further, it is noted that the claimed peptides can be as short as 3 amino acids and as long as "about 100" amino acids. These limitations raise significant issues of unpredictability as it is highly unlikely that a 3 amino acid peptide could comprise a functional antibody binding site (i.e., an anti-mimotope) while a peptide of 100 or more amino acids could comprise additional structural features such as intra-chain disulfide bonds and the ability to form β sheets (which requires a peptide of ~20 amino acids, see Mayo, of record). As the asserted functional peptides of the instant claims consist of 10mers exclusively, said peptides are insufficient to enable either the very short, or very long peptides encompassed by the instant claims. It is also noted that the references Applicant cites in support of the instant peptides also generally teach only short peptides. See for example, Cwirla et al. or Balass et al. which teach hexapeptides or Christian et al. which teaches decapeptides. None of the references teach libraries of 3mers or 100mers as would be required to isolate the peptides recited in the instant claims. Thus, it remains the Examiner's position that contrary to Applicant's assertions, the instant application fails to disclose how to make the peptides encompassed by the breadth of the instant claims without undue experimentation.

8. The following are New Grounds for Rejection.

9. Claim 9 and 11 is rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically: "an isolated peptide of 3 to about 100 amino acids residues."

Applicant's amendment, filed 5/25/01, fails to assert that no new matter has been added and no support for the newly claimed limitation of "about 100 amino acids" has been found in the specification.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claim comprises a recitation of product-by process. The product is "an isolated peptide," thus the process must result in an isolated peptide. The process, however, results in "identifying the screened test peptides." Note both the plural peptides and the lack of a final isolation of a product. Thus, the claim is vague and indefinite as the process does not provide a means to the claimed product.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be

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directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
July 25, 2001